IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804
	Case No. 1:17-md-2804
THIS DOCUMENT RELATES TO ALL CASES	Judge Dan Aaron Polster

AMNEAL DEFENDANTS' STATUS REPORT
IN ACCORDANCE WITH APRIL 21, 2022, ORDER

Pursuant to the Court's April 21, 2022 Order, Defendants Amneal Pharmaceuticals LLC ("AP LLC"), Amneal Pharmaceuticals of New York, LLC ("AP NY LLC"), and Amneal Pharmaceuticals, Inc. ("API") (collectively "Amneal Defendants"), submit the following status report.[1]

I. BACKGROUND

Although Amneal Defendants are named in a subset of cases that are pending in the MDL, they have not been involved in any discovery that has been conducted in the MDL to date.

AP LLC and AP NY LLC are limited liability companies organized under the laws of the state of Delaware with their principle places of business in New Jersey and New York, respectively. AP LLC and AP NY LLC have manufactured and sold only generic opioid medications under Abbreviated New Drug Applications approved by the federal Food and Drug Administration ("FDA"), and they do not advertise or promote those medications in the United States. The business model under which generic companies operate is vastly different than the way in which brand companies market and promote their products. No physician prescribes a specific

[1] For convenience and pursuant to the Court's April 21, 2022, Order (Dkt. No. 4380), the Amneal Defendants provide this consolidated status report. However, each Amneal Defendant expressly preserves and does not waive all of its rights, reservations, objections, and arguments, including with respect to service and lack of personal jurisdiction.

generic drug manufacturer's opioid containing medication. The physician or other prescriber may prescribe a brand drug, in which case the generic products are then generally substituted for the more expensive branded products by pharmacists. *See, e.g.*, Ohio Rev. Code § 4729.38; W. Va. Code § 30-5-12B(b) ("A pharmacist who receives a prescription for a brand name drug or drug product shall substitute a less expensive equivalent generic name drug or drug product . . ."). Alternatively, a physician or other prescriber may have prescribed an opioid containing medication using its chemical name (e.g., hydrocodone), but he or she would have no idea (and no interest in knowing) which generic drug manufacturer's hydrocodone was dispensed to her or his patient.

Which generic drug manufacturer's opioid containing medications are dispensed to a patient is a result of a series of contracts based on price and supply factors. Generic drug manufacturers like the Amneal Defendants do not have sales representatives that call on physicians or other prescribers about their generic opioid medications, and they do not promote those products to physicians or other prescribers in any other manner. That is not a matter of any principled or reasonable dispute, notwithstanding the indiscriminate lumping of the Amneal Defendants into contrary allegations in plaintiffs' complaints.[2]

While the Amneal Defendants are open to exploring a path by which the cases ultimately will be resolved, there are numerous threshold issues that need to be addressed for there to be any prospect of meaningful settlement discussions. One threshold issue is that Amneal Defendants do not yet have information regarding which cases plaintiffs actually intend to pursue against them. As part of the Court's April 21 Order, plaintiffs are required to provide "notice of how and whether

[2] API is a holding company that was formed under the laws of Delaware, on October 4, 2017, with its principal place of business in New Jersey. It does not manufacture, promote, distribute, or sell opioids anywhere in the United States. For this reason, API is an improper party to this litigation, including for the reason that there is no personal jurisdiction over API in any case in which it is named. The naming of API in the cases is another example of the lack of any attempt by plaintiffs to plead facts and their reliance on an indiscriminate "lumping in" approach to their complaints.

Plaintiffs intend to proceed against each of the above-listed Defendants." Amneal Defendants intend to evaluate the information submitted by plaintiffs to determine which cases plaintiffs intend to pursue against them. For those plaintiffs that intend to pursue cases against the Amneal Defendants, there are multiple other threshold issues:

> **Plaintiff Fact Sheets:** Amneal Defendants do not currently have access to plaintiff fact sheets for all cases in which they are named as required by the June 19, 2018 Order [Dkt. 638]. Amneal Defendants were added to the vast majority of cases in which they are named through amended complaints in 2019 or later, and are unable to determine whether fact sheets in those cases were previously produced by plaintiffs. The Amneal Defendants view the receipt of complete and accurate fact sheets from plaintiffs intending to pursue claims against them as an essential prerequisite to any settlement discussions. Related to the Fact Sheets issue is the concern that relative to the Court's Order, Nov. 8, 2018, Order Regarding Plaintiff's Motion for Modification of CMO-1 (Dkt. No. 1106), Amneal Defendants are currently named in a significant number of complaints in which they have limited market share in ARCOS.
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> **Lack of Service:** The plaintiffs in many of the cases in which Amneal Defendants are named have not attempted to serve the Amneal Defendants, and the time to do so for those cases has long since passed.
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> **Lack of Personal Jurisdiction:** With respect to API, there is no personal jurisdiction over that entity because it does not manufacture, promote, distribute, or sell opioids anywhere in the United States. Additionally, there are numerous cases in which there is no personal jurisdiction over any of the Amneal Defendants.

In addition to the threshold issues discussed above, Amneal Defendants had no involvement in the conduct that allegedly created the circumstances that have led to opioid litigation. In other words, plaintiffs have built their public nuisance theories (and related theories) against manufacturers on the premise that promotion of opioid medications to physicians and other prescribers created the alleged nuisance.[3] Plaintiffs have then asserted that those manufacturers who allegedly created the nuisance had an obligation to abate it. As described above, that litigation model does not fit generic drug manufacturers like the Amneal Defendants, and there are

[3] That is equally true for manufacturers that manufactured and sold both brand opioid containing medication and generic opioid containing medications. Stated another way, those manufacturers did not manufacture and sell exclusively generic opioid containing medications.

significant factual and legal differences between the cases against manufacturers that have come before and cases against the Amneal Defendants. As to the legal differences, while the Amneal Defendants' position is that there is no basis for application of public nuisance theory against manufacturers generally, there is a significant difference within that theory between an entity that allegedly created the nuisance and an unconnected entity that is being asked to abate the nuisance. The fundamental difference in how generic companies operate explains plaintiffs' failure to recognize the limited role generic manufacturers play in the allegations, or striking lack thereof, asserted in the complaints. The cases naming Amneal Defendants depend upon formulaic representations and do not include any specific *factual* allegations of wrongdoing by any Amneal Defendants and in many cases they attribute conduct to Amneal Defendants that is not accurate.

II. RESPONSE TO APRIL 21 ORDER

A. BELLWETHER SELECTION IS PREMATURE

The Court's April 21 Order requests that the parties provide their position on whether and how the Court should conduct additional bellwether trials. Given the context described above, the Amneal Defendants respectfully submit that bellwether selection as to the second tier group of manufacturers of generic medications only is premature at this juncture. In addition to the issues outlined above, Amneal Defendants are engaged in discovery and other pretrial proceedings in numerous other cases across the country. Those cases involve a variety of different plaintiffs, including political subdivisions, hospitals, and individual personal injury plaintiffs. Amneal Defendants also have two trials scheduled to begin in the first half of next year (including one case brought by hospital systems).[4] Further, in the absence of the basic threshold information described

[4] Trials involving the Amneal Defendants currently scheduled for the first half of 2023 are *Mobile County Board of Health, et al. v. AmerisourceBergen Drug Corporation, et al.*, Civil Action No. 02-CV-2019-902806 (Mobile County, AL, January 9, 2023), and *The DCH Health Care Authority, et al. v. Purdue Pharma L.P., et al., No. CV-2019-000007.00* (Conecuh County, AL, March 20, 2023).

above, Amneal is not in a position to know what, if any, issues might be informed by bellwether testing, much less to propose specific cases that would provide appropriate vehicles for a bellwether trial. Additionally, allowing the parties an opportunity to engage in settlement discussions and/or a mediation prior to selecting bellwethers in this Court may obviate the need for bellwether selections here and conserve this Court's resources.

B. POSITION ON SETTLEMENT

Despite the obstacles plaintiffs face in prevailing against Amneal Defendants, Amneal Defendants would be willing to participate in a private mediation. The Amneal Defendants respectfully request that the Court first provide the parties with an opportunity to evaluate plaintiffs' submission and resolve the threshold issues identified above. The parties have not yet had an opportunity to discuss the factual and legal bases of plaintiffs' claims against the Amneal Defendants, which as described above are different from prior claims against other manufacturers. In the absence of such basic information, Amneal is not in a position to comment more specifically on a possible mediation plan.

Respectfully submitted,

/s/ Paul J. Cosgrove

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CERTIFICATE OF SERVICE

The undersigned certifies on June 16, 2022, the foregoing was filed using the Court's CM/ECF system and will be served via the Court's CM/ECF filing system on all attorneys of record.

/s/ *Paul J. Cosgrove*